

IN THE UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF PENNSYLVANIA

SUSAN JEFFERIES and BRYAN  
JEFFERIES,

Plaintiffs,

v.

BOEHRINGER INGELHEIM  
PHARMACEUTICALS, INC., a Connecticut  
corporation; PFIZER INC., a New York  
corporation; PHARMACIA  
CORPORATION, a Delaware corporation;  
and PHARMACIA & UPJOHN  
COMPANY LLC,

Defendants.

No.: 09-cv-3432

ANSWER AND AFFIRMATIVE DEFENSES OF  
DEFENDANTS PFIZER INC., PHARMACIA CORPORATION,  
AND PHARMACIA & UPJOHN COMPANY LLC TO  
PLAINTIFFS' COMPLAINT; AND REQUEST FOR JURY TRIAL

Defendants Pfizer Inc., Pharmacia Corporation, and Pharmacia & Upjohn Company LLC (collectively referred to herein as "Answering Defendants"), by and through their counsel, Reed Smith LLP, hereby submit their Answer and Affirmative Defenses to plaintiffs' Complaint and in support thereof, aver as follows:

PARTIES, JURISDICTION & VENUE

1. Answering Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 1 of plaintiffs' Complaint, and therefore deny the same.
2. Answering Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 2 of plaintiffs' Complaint, and therefore deny the same.

3. Answering Defendants deny the allegation in Paragraph 3 of plaintiffs' Complaint.

4. Answering Defendants admit that Pfizer Inc. is a Delaware Corporation with its principle place of business in New York, New York and is authorized to do business in Pennsylvania with an agent for service of process in Pennsylvania.

5. The allegations in Paragraph 5 of plaintiffs' Complaint are not directed to Answering Defendants and, therefore, no response is required.

6. Answering Defendants admit that Pharmacia Corporation is a Delaware Corporation with its principle place of business in Peapack, New Jersey and is authorized to do business in Pennsylvania with an agent for service of process in Pennsylvania. Answering Defendants admit that Pharmacia Corporation is wholly-owned by Pfizer Inc. Answering Defendants deny the remaining allegations in Paragraph 6 of plaintiffs' Complaint.

7. Answering Defendants admit that Pharmacia & Upjohn Company LLC is a limited liability company whose sole member is Pharmacia & Upjohn LLC, whose sole member is Pharmacia Corporation, which is wholly owned by Pfizer Inc. Answering Defendants admit that Pharmacia & Upjohn Company LLC is authorized to do business in Pennsylvania with an agent for service of process in Pennsylvania. Answering Defendants deny the remaining allegations in Paragraph 7 of plaintiffs' Complaint.

8. Answering Defendants admit that from July 1997 to May 2005, they jointly promoted and marketed Mirapex® ("Mirapex") with Boehringer Ingelheim Pharmaceuticals, Inc. ("BIPI") throughout the United States. Answering Defendants deny the remaining allegations in Paragraph 8 of plaintiffs' Complaint.

9. Answering Defendants state that the statutory allegations in Paragraph 9 of plaintiffs' Complaint are legal conclusions to which no response is required. Answering Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 2 of plaintiffs' Complaint regarding where plaintiffs reside. Answering Defendants deny the remaining allegations in Paragraph 9 of plaintiffs' Complaint.

10. Answering Defendants admit that from July 1997 to May 2005, they jointly promoted and marketed Mirapex with BIPI throughout the United States.

**FACTUAL BACKGROUND**  
**(Defendants)**

11. Answering Defendants admit that from July 1997 to May 2005, they jointly promoted and marketed Pramipexole Tablets under the brand name Mirapex with BIPI throughout the United States. Defendants admit that Mirapex is indicated for the treatment of the signs and symptoms of Restless Legs Syndrome ("RLS") and Parkinson's disease, and further state that the medical symptoms, conditions or treatment of these diseases have been described in the peer reviewed medical literature. Answering defendants further state that the allegations in Paragraph 11 of plaintiffs' Complaint call for medical opinions and conclusions.

12. Answering Defendants admit that RLS is a neurological disorder, and state that its medical symptoms, conditions and treatment have been described in the peer reviewed medical literature. Answering defendants further state that the allegations in Paragraph 12 of plaintiffs' Complaint call for medical opinions and conclusions.

13. Answering Defendants admit that Mirapex is within the class of drugs known as dopamine agonists. Answering Defendants further state that the pharmacologic effects of dopamine agonists are described in the peer reviewed medical literature.

14. Answering Defendants admit that Mirapex binds with certain dopamine receptors. Answering Defendants further state that the identity of dopamine receptors and the pharmacologic effects of dopamine agonists are described in the peer reviewed medical literature. Answering Defendants further admit that in December 1995, The Upjohn Company submitted a New Drug Application (“NDA”), NDA 20-667, for Pramipexole Tablets containing doses of 0.125 mg, 1.0 mg, 1.25 mg and 1.5 mg and indicated for the treatment of Parkinson’s disease. Answering Defendants admit that the FDA approved the Mirapex NDA in July 1997. Answering Defendants further admit that the FDA approved Mirapex for the treatment of RLS in November 2006. Answering Defendants deny the remaining allegations in Paragraph 14 of plaintiffs’ Complaint.

15. Answering Defendants deny the allegations in Paragraph 15 of plaintiffs’ Complaint.

16. Answering Defendants admit that BIPI changed the Mirapex label and that the changes are reflected in the package insert and speak for themselves. Answering Defendants deny the remaining allegations in Paragraph 16 of plaintiffs’ Complaint.

17. Answering Defendants deny the allegations in Paragraph 17 of plaintiffs’ Complaint.

18. Answering Defendants admit that in August 2003, Dr. Mark Stacy published a retrospective analysis in the journal *Neurology* which discussed dopamine agonists and pathological gambling as alleged in Paragraph 18 of plaintiffs’ Complaint. Answering Defendants state that the analysis speaks for itself.

19. Answering Defendants admit that physicians at the Mayo Clinic published a case report in the *Archives of Neurology* in August 2005 which discussed dopamine agonists and

pathological gambling as alleged in Paragraph 19 of plaintiff's Complaint. Answering Defendants state that the report speaks for itself.

20. Answering Defendants admit that a study was published in the journal *Neurology* in January 2007 which discussed dopamine agonists and pathological gambling as alleged in Paragraph 20 of plaintiff's Complaint. Answering Defendants state that the report speaks for itself.

21. Answering Defendants deny the allegations in Paragraph 21 of plaintiffs' Complaint.

**FACTUAL BACKGROUND**  
**(Plaintiff, Susan Jefferies)**

22. Answering Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 22 of plaintiffs' Complaint, and therefore deny the same.

23. Answering Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 23 of plaintiffs' Complaint, and therefore deny the same.

24. Answering Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 24 of plaintiffs' Complaint, and therefore deny the same.

25. Answering Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 25 of plaintiffs' Complaint, and therefore deny the same.

26. Answering Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 26 of plaintiffs' Complaint, and therefore deny the same.

27. Answering Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 27 of plaintiffs' Complaint, and therefore deny the same.

28. Answering Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 28 of plaintiffs' Complaint, and therefore deny the same.

29. Answering Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 29 of plaintiffs' Complaint, and therefore deny the same.

**FIRST CAUSE OF ACTION**

**(Strict Liability – Design, Manufacturing and Warning – in Tort against all Defendants)**

Answering Defendants incorporate by reference their responses to the above paragraphs as if fully set forth herein.

30. Answering Defendants state that Paragraph 30 of plaintiff's Complaint contains legal conclusions, to which no response is required. To the extent a response is necessary, Answering Defendants admit that they had, at various times, regulatory and other duties related to Mirapex. Answering Defendants deny all remaining allegations in Paragraph 30 of plaintiff's Complaint.

31. Answering Defendants deny the allegations in Paragraph 31 of plaintiffs' Complaint.

32. Answering Defendants deny the allegations in Paragraph 32 of plaintiffs' Complaint.

33. Answering Defendants deny the allegations in Paragraph 33 of plaintiffs' Complaint.

34. Answering Defendants deny the allegations in Paragraph 34 of plaintiffs' Complaint.

35. Answering Defendants deny the allegations in Paragraph 35 of plaintiffs' Complaint.

**SECOND CAUSE OF ACTION**  
**(Breach of Express Warranty by Defendants)**

Answering Defendants incorporate by reference their responses to the above paragraphs as if fully set forth herein.

36. Answering Defendants deny the allegations in Paragraph 36 of plaintiffs' Complaint.

37. Answering Defendants deny the allegations in Paragraph 37 of plaintiffs' Complaint.

38. Answering Defendants deny the allegations in Paragraph 38 of plaintiffs' Complaint.

**THIRD CAUSE OF ACTION**  
**(Breach of Implied Warranty)**

Answering Defendants incorporate by reference their responses to the above paragraphs as if fully set forth herein.

39. Answering Defendants deny the allegations in Paragraph 39 of plaintiffs' Complaint.

40. Answering Defendants deny the allegations in Paragraph 40 of plaintiffs' Complaint.

41. Answering Defendants deny the allegations in Paragraph 41 of plaintiffs' Complaint.

42. Answering Defendants deny the allegations in Paragraph 42 of plaintiffs' Complaint.

**FOURTH CAUSE OF ACTION**  
**(Negligence)**

Answering Defendants incorporate by reference their responses to the above paragraphs as if fully set forth herein.

43. Answering Defendants state that Paragraph 43 of plaintiff's Complaint contains legal conclusions, to which no response is required. To the extent a response is necessary, Answering Defendants admit that they had, at various times, regulatory and other duties related to Mirapex. Answering Defendants deny all remaining allegations in Paragraph 43 of plaintiff's Complaint.

44. Answering Defendants deny the allegations in Paragraph 44 of plaintiffs' Complaint.

45. Answering Defendants deny the allegations in Paragraph 45 of plaintiffs' Complaint.

46. Answering Defendants deny the allegations in Paragraph 46 of plaintiffs' Complaint.



**FIFTH CAUSE OF ACTION**

**(Negligence Per Se)**

**(Violation of 21 U.S.C. §§ 331, 352 and 21 C.F.R. §§ 201.56, 201.57, 202.1)**

Answering Defendants incorporate by reference their responses to the above paragraphs as if fully set forth herein.

47. Answering Defendants state that Paragraph 47 of plaintiff's Complaint contains legal conclusions, to which no response is required. To the extent a response is necessary, Answering Defendants admit that they had, at various times, regulatory and other duties related to Mirapex. Answering Defendants deny all remaining allegations in Paragraph 47 of plaintiffs' Complaint.

48. Answering Defendants deny the allegations in Paragraph 48 and its subparagraphs a. through d. of plaintiffs' Complaint.

49. Answering Defendants state that Paragraph 49 of plaintiff's Complaint contains legal conclusions, to which no response is required. Answering Defendants deny that they violated any statutes or regulations.

50. Answering Defendants deny the allegations in Paragraph 50 of plaintiffs' Complaint.

**SIXTH CAUSE OF ACTION**

**(Negligent Misrepresentation)**

Answering Defendants incorporate by reference their responses to the above paragraphs as if fully set forth herein.

51. Answering Defendants deny the allegations in Paragraph 51 of plaintiffs' Complaint.

52. Answering Defendants deny the allegations in Paragraph 52 of plaintiffs' Complaint.

53. Answering Defendants deny the allegations in Paragraph 53 of plaintiffs' Complaint.

54. Answering Defendants deny the allegations in Paragraph 54 of plaintiffs' Complaint.

55. Answering Defendants deny the allegations in Paragraph 55 of plaintiffs' Complaint.

56. Answering Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 56 of plaintiffs' Complaint regarding plaintiff's, her physicians' and the general public's belief or regarding plaintiff's or her physicians' reliance and therefore deny the same.

57. Answering Defendants deny the allegations in Paragraph 57 of plaintiffs' Complaint.

**SEVENTH CAUSE OF ACTION**  
**(Loss of Consortium)**

Answering Defendants incorporate by reference their responses to the above paragraphs as if fully set forth herein.

58. Answering Defendants deny the allegations in Paragraph 58 of plaintiffs' Complaint.

**DEMAND FOR RELIEF**

Answering Defendants deny that plaintiffs are entitled to the relief demanded in their Complaint.

**GENERAL DENIAL**

Answering Defendants deny all allegations and/or legal conclusions set forth in plaintiffs' Complaint that have not previously been specifically admitted, denied, or explained.

### **AFFIRMATIVE DEFENSES**

Discovery and investigation may reveal that any one or more of the following defenses should be available to Answering Defendants in this matter. Answering Defendants therefore assert the following defenses in order to preserve the right to assert them. Upon completion of discovery, if the facts warrant, Answering Defendants will withdraw any of these defenses as may be appropriate.

#### **First Defense**

1. The Complaint fails to state a claim upon which relief may be granted.

#### **Second Defense**

2. The claims asserted in the Complaint are barred, in whole or part, by the applicable statute(s) of limitations and/or repose, by the applicable doctrines of laches, waiver, estoppel, and/or illegality.

#### **Third Defense**

3. The claims asserted in the Complaint are barred, in whole or part, because plaintiffs lack standing and/or capacity to bring such claims.

#### **Fourth Defense**

4. Plaintiffs' claims may be barred, in whole or in part, due to plaintiffs' failure to join indispensable parties and/or bring claims against the real party in interest.

#### **Fifth Defense**

5. Answering Defendants assert that plaintiffs filed this Complaint in an improper forum, and therefore, venue is improper.

**Sixth Defense**

6. The claims asserted in the Complaint are barred, in whole or in part, because the advertisements, if any, and labeling with respect to the product, was not false or misleading, and therefore constitute protected commercial speech under the applicable provisions of the Constitution of the United States.

**Seventh Defense**

7. The claims asserted in the Complaint are barred, in whole or in part, because plaintiffs may not have suffered injuries or a significantly increased risk of contracting serious latent diseases or injuries as a result of Mirapex use.

**Eighth Defense**

8. The claims asserted in the Complaint are barred, in whole or in part, because plaintiffs lack an adequate scientific basis to demonstrate any resulting harm or increased risk of future harm as a result of plaintiffs' alleged Mirapex use.

**Ninth Defense**

9. The claims asserted in the Complaint are barred, in whole or in part, because Mirapex possesses no characteristic which renders it unreasonably dangerous in a reasonably anticipated use by an individual.

**Tenth Defense**

10. Plaintiffs' injuries, if any, may be due to an allergic, idiosyncratic, or idiopathic reaction to Mirapex, or by an unforeseeable illness, unavoidable acts, or preexisting condition without any negligence or culpable conduct by Answering Defendants.

**Eleventh Defense**

11. Plaintiffs have not suffered, and will not suffer, any injury to a legally protected or cognizable interest or any damage by reason of the conduct of Answering Defendants as alleged in the Complaint.

**Twelfth Defense**

12. The claims asserted in the Complaint are barred, in whole or in part, because plaintiff would have taken the product even if the product labeling contained the information plaintiffs contend should have been provided.

**Thirteenth Defense**

13. Plaintiffs' claims are barred because plaintiffs knew of the alleged risks of Mirapex or because a reasonable purchaser and/or consumer would have been aware of the alleged risks of Mirapex.

**Fourteenth Defense**

14. The claims asserted in the Complaint are barred, in whole or in part, because the utility and/or therapeutic benefits of Mirapex outweigh the risk.

**Fifteenth Defenses**

15. Plaintiffs' claims as set forth in the Complaint are barred to the extent that plaintiff misused or abused Mirapex, failed to use Mirapex properly, and/or used Mirapex negligently or used it in any other way except that for which it was intended.

**Sixteenth Defense**

16. Plaintiffs' claims are barred in whole or in part by lack of defect, as any product allegedly ingested by plaintiff was properly prepared in accordance with the applicable standard of care.

**Seventeenth Defense**

17. The claims asserted in the Complaint are barred, in whole or in part, by the learned intermediary doctrine.

**Eighteenth Defense**

18. The claims asserted in the Complaint are barred as a matter of law pursuant to the Restatement (Third) of Torts: Product Liability § 4, et seq., because Mirapex complied with applicable product safety statutes and administrative regulations.

**Nineteenth Defense**

19. The claims asserted in the Complaint are barred as a matter of law pursuant to the Restatement (Third) of Torts: Product Liability §§ 6(c), 6(d), and comment f.

**Twentieth Defense**

20. The claims asserted in the Complaint are barred as a matter of law pursuant to Restatement (Second) of Torts § 402A, comments j & k.

**Twenty-First Defense**

21. The claims asserted in the Complaint are barred, in whole or in part, because Mirapex was designed, tested, manufactured, and labeled in accordance with state-of-the-art and industry standards existing at the time of sale and conformed to the generally recognized, reasonably available and reliable state of knowledge in the field at the time Mirapex was manufactured.

**Twenty-Second Defense**

22. The claims set forth in the Complaint are barred because the methods, standards and techniques used in formatting Mirapex and in issuing warnings and instructions about its use

conformed to the generally recognized, reasonably available and reliable state of knowledge in the field at the time Mirapex was manufactured.

**Twenty-Third Defense**

23. The claims asserted in the Complaint are barred, in whole or in part, because the manufacturing, labeling, packaging, and any advertising of the product complied with the applicable codes, standards, and regulations established, adopted, promulgated, or approved by any regulatory body with jurisdiction over the product, including but not limited to the United States, any state, and any agency thereof.

**Twenty-Fourth Defense**

24. The claims asserted in the Complaint are barred, in whole or in part, by the doctrine of abstention, in that the common law gives deference to discretionary actions by the FDA under the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 et seq.

**Twenty-Fifth Defense**

25. The claims asserted in the Complaint are barred, in whole or in part, because Mirapex is comprehensively regulated by the FDA pursuant to the FDCA, and regulations promulgated thereunder, and plaintiffs' claims conflict with the FDCA, with the regulations promulgated by the FDA to implement the FDCA, with the purposes and objectives of the FDCA and the FDA's implementing regulations, and with the specific determinations by the FDA specifying the language that should be used in the labeling accompanying the products. Accordingly, plaintiffs' claims are preempted by the Supremacy Clause of the Constitution of the United States, Article VI, clause 2, and the laws of the United States, including but not limited to the FDCA and the regulations promulgated thereunder. Alternatively Answering Defendants are

entitled to a presumption based on the FDA's approval of Mirapex that the product is not defective or unreasonably dangerous.

**Twenty-Sixth Defense**

26. The conduct of Answering Defendants and all activities with respect to the subject product have been and are under the supervision of the FDA. Accordingly, this action, including any claims for monetary and/or injunctive relief, is barred by the doctrine of primary jurisdiction and exhaustion of administrative remedies.

**Twenty-Seventh Defense**

27. The claims asserted in the Complaint are barred by the doctrine of implied preemption to the extent they are premised on alleged misrepresentations or misstatements to the FDA. *See Buckman Co. v. Plaintiff's Legal Committee*, 531 U.S. 341 (2001).

**Twenty-Eight Defense**

28. To the extent the claims asserted in the Complaint are based on a theory providing for liability without proof of causation, the claims violate Answering Defendants' rights under the Constitution of the United States and analogous provisions of the applicable states' constitutions.

**Twenty-Ninth Defense**

29. If plaintiffs sustained any damages as alleged, said damages resulted from an intervening or superseding cause and/or causes, and any act or omission on the part of Answering Defendants was not the proximate and/or competent producing cause of such alleged damages.



**Thirtieth Defense**

30. The alleged injuries to plaintiffs may have been caused, in whole or in part, by plaintiffs' own acts and omissions, including, but not limited to, misuse, unintended use, abuse, and/or failure to properly utilize Answering Defendants' products, and plaintiffs' comparative negligence or fault is sufficient to bar these claims, or to proportionately reduce plaintiffs' recovery.

**Thirty-First Defense**

31. If plaintiffs sustained any damages as alleged, such damages arose from, and may have been caused by, risks, hazards, and dangers knowingly assumed by plaintiffs. Plaintiffs' recovery accordingly may be barred or should be reduced by his assumption of the risk.

**Thirty-Second Defense**

32. Plaintiffs' alleged injuries and damages, if any, were of independent, unforeseeable, superseding, and/or intervening causes unrelated to any conduct of Answering Defendants or plaintiff's alleged ingestion of Mirapex.

**Thirty-Third Defense**

33. If plaintiffs sustained any damages as alleged, said damages may have been solely caused by the acts or omissions, abuse or misuse, negligence, or fault, of others over whom Answering Defendants had no control or right to control and whose actions are not, therefore, imputable to Answering Defendants.

**Thirty-Fourth Defense**

34. The claims set forth in the Complaint are barred because the alleged injuries and damages, if any, were caused by medical conditions, disease, illness or processes (whether pre-existing or contemporaneous) unrelated to Mirapex.

**Thirty-Fifth Defense**

35. Plaintiffs' alleged injuries and damages were not proximately caused by an act or omission of Answering Defendants.

**Thirty-Sixth Defense**

36. Answering Defendants are entitled to any credit for any settlement of claims for alleged injuries and damages made by plaintiffs with any other defendant, person or entity.

**Thirty-Seventh Defense**

37. To the extent plaintiffs obtain recovery in any other case predicated on the same factual allegations, plaintiffs are barred from seeking recovery against Answering Defendants based on the Complaint pursuant to the doctrines of res judicata and collateral estoppel, and the prohibition on double recovery for the same injury.

**Thirty-Eighth Defense**

38. To the extent applicable, Answering Defendants are entitled to contribution from any person and/or entity whose negligence or other fault contributed to plaintiffs' alleged injuries and damages.

**Thirty-Ninth Defense**

39. The claims asserted in the Complaint may be barred, in whole or in part, by plaintiffs' failure to exercise reasonable care and diligence to mitigate plaintiffs' damages, if any.

**Fortieth Defense**

40. Plaintiffs' losses, if any, are subject to an offset for benefits received by plaintiffs resulting from the alleged use of Mirapex.

**Forty-First Defense**

41. To the extent applicable, Answering Defendants specifically assert the defense of contributory negligence and the doctrine of comparative fault.

**Forty-Second Defense**

42. In the event that it is determined that plaintiffs are entitled to recover against Answering Defendants, plaintiffs' recovery should be reduced in proportion to the degree or percentage of negligence, fault or exposure to products attributable to plaintiffs or others, including any party immune because bankruptcy renders them immune from further litigation, as well as any party, co-defendant or non-parties with whom plaintiffs have settled or may settle in the future.

**Forty-Third Defense**

43. To the extent plaintiffs are alleging fraud or similar conduct, plaintiffs have failed to plead fraud with sufficient particularity.

**Forty-Fourth Defense**

44. Answering Defendants incorporate by reference the affirmative defenses set forth by any other defendant in this action to the extent consistent with Answering Defendants' Answer as though fully set forth herein, and Answering Defendants hereby give notice of their intention to rely upon such other affirmative defenses as may become available or apparent during the course of discovery and reserves the right to amend its Answer to assert such defenses.

**Forty-Fifth Defense**

45. To the extent applicable, the Complaint fails to state facts sufficient to sustain a claim for, or recovery of, punitive or exemplary damages.

**Forty-Sixth Defense**

46. Answering Defendants allege that plaintiffs' claims for punitive or exemplary damages are barred or reduced by applicable law or statute or, in the alternative, are unconstitutional insofar as they violate the due process protections afforded by the United States Constitution, the excessive fines clause of the Eighth Amendment of the United States Constitution, the Commerce Clause of the United States Constitution, and the Full Faith and Credit Clause of the United States Constitution. Any law, statute or other authority purporting to permit the recovery of punitive damages in this case is unconstitutional, facially and as applied, to the extent that, without limitation, it: (1) lacks constitutionally sufficient standards to guide and restrain the jury's discretion in determining whether to award punitive damages and/or the amount, if any; (2) is void for vagueness in that it failed to provide adequate advance notice as to what conduct will result in punitive damages; (3) unconstitutionally may permit recovery of punitive damages based on out-of-state conduct, conduct that complied with applicable law, or conduct that was not directed, or did not proximately cause harm, to plaintiff; (4) unconstitutionally may permit recovery of punitive damages in an amount that is not both reasonable and proportionate to the amount of harm, if any, to plaintiff and to the amount of compensatory damages, if any; (5) unconstitutionally may permit jury consideration of net worth or other financial information relating to Answering Defendants; (6) lacks constitutionally sufficient standards to be applied by the trial court in post-verdict review of any punitive damages award; (7) lacks constitutionally sufficient standards for appellate review of punitive damages awards; and (8) otherwise fails to satisfy Supreme Court precedent, including, without limitation, *Pacific Mutual Life Ins. Co. v. Haslip*, 499 U.S. 1, 111 S.Ct. 1032 (1991); *TXO Production Corp. v. Alliance Resources, Inc.*, 509 U.S. 443, 113 S.Ct. 2711 (1993); *BMW of*

*North America, Inc. v. Gore*, 517 U.S. 559, 116 S.Ct. 1589 (1996); and *State Farm Ins. Co. v. Campbell*, 123 S.Ct. 1513 (2003).

**Forty-Seventh Defense**

47. To the extent not incorporated above, Answering Defendants raise all affirmative defenses available under the law of the forum in which the alleged cause of action arose.

**REQUEST FOR JURY TRIAL**

Answering Defendants request a trial by jury on all issues triable.

**PRAYER FOR RELIEF**

WHEREFORE, Answering Defendants pray for relief from judgment for plaintiffs as follows:

1. Plaintiffs take nothing by reason of their Complaint.
2. Answering Defendants recover their costs and attorneys' fees incurred herein;
3. For a trial by jury on all issues so triable; and
4. For such further and other relief as the Court deems proper.

REED SMITH LLP

By /s/ William J. McDonough

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Pharmacia Corporation, and Pharmacia  
and Upjohn Company LLC*

Dated: August 4, 2009

**CERTIFICATE OF SERVICE**

I hereby certify that on this 4<sup>th</sup> day August, 2009, a copy of the foregoing Answer and Affirmative Defenses of Defendants Pfizer Inc., Pharmacia Corporation, And Pharmacia & Upjohn Company LLC to Plaintiffs' Complaint; and Request for Jury Trial was sent via electronic and first-class mail, postage prepaid, to:

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